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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,777	09/15/2003	Hassan Ahmad	2551-1-001	1508
23565	7590	01/03/2006		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,777

Applicant(s)

AHMAD ET AL.

Examiner

S. B. McCormick-Ewoldt

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1655

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2005 has been entered.

Amendments

The amendment of November 7, 2005 is hereby acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I and the species, *Nigella sativa*, in the reply filed February 24, 2005. Claims 11-25 are withdrawn from further consideration.

Claims Pending

Applicant has cancelled claim 3 and added claims 26-28. Claims 1-2, 4-10 and 26-28 will be examined on the merits and solely with regard to the elected species, *Nigella sativa*.

Claim Rejections - 35 USC § 102

The rejection of 35 U.S.C. 102(b) has been withdrawn in view of Applicant's amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by

Art Unit: 1655

another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-10 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby *et al.* (US 2002/0160065 A1).

Shalaby *et al.* (US 2002/0160065 A1) expressly teaches using *Nigella sativa* in a composition with antiviral properties to treat infections with hepatitis B virus or hepatitis C virus using about 11.5% to about 34.5% by weight. In addition, Shalaby *et al.* disclose the various techniques the composition can be administered such as intranasal, rectal, transdermal, tablets, capsules, patches, solutions and suspensions. Therefore, the teaching of Shalaby *et al.* meets the limitations of claims 1, 2, 4 and thus anticipates the claimed invention.

Claim Rejections - 35 USC § 103

Claims 1, 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shawkat (US 5,648,089) for the reasons set forth in the previous Office action.

Shawkat (US 5,648,089) teaches using *Nigella sativa* in an oral herb composition to treat patients diagnosed with active Hepatitis-B and Hepatitis-C (column 1, lines 20-35, 60 and claim 1). The reference does not specifically teach the ingredients in the dosage forms claimed by Applicant. The dosage form of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the dosage form of each ingredient in order to best achieve the desired results. The reference also does not specifically teach the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results.

Response to Arguments

Applicant's arguments filed November 7, 2005 have been fully considered but they are not persuasive.

Art Unit: 1655

Applicant argues that Shawkat does not teach or suggest a therapeutically amount not less than 20% weight per volume of *Nigella sativa* present. This is not persuasive because one skilled in the art would be motivated to modify amounts of a specific ingredient to see which amount would work the best to treat the disease.

As discussed *supra*, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In response to **Applicant's argument** that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regards to the results on pages 5-14 of the declaration dated July 1, 2005, the Examiner has considered the results. Applicant argues clinical trials which show decreasing the hepatitis virus. Applicant argues that amounts below 20% do not function as well. Thus, Applicant contends that unexpected results stem from the claimed amounts. However, Applicant does not show any data using a lower dosage. Thus, a comparison between the claimed amount and the amounts in the prior art is not clear. Therefore, the declaration is not considered to support unexpected results.

Therefore, the rejection is deemed proper and is maintained.

Summary

No claim is allowed.

Art Unit: 1655

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Terry McKelvey, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
12-21-05

SUSAN COE
PRIMARY EXAMINER